

Summary of Safety and Effectiveness:

Name of Device: Serum CrossLaps™ One Step ELISA
Classification Name: Enzyme immunoassay, Type I Collagen C-Telopeptide
Analyte Code and Name: JMM

Submitter: Osteometer BioTech A/S
Herlev Hovedgade 207
DK-2730 Herlev

Date: March 9th, 1999

The Serum CrossLaps™ One Step ELISA kit was developed for the quantitative measurement of Type I Collagen C-Telopeptide (CrossLaps™) in human plasma and serum.

The EIA format is a non-competitive binding protein assay.

The Serum CrossLaps™ One Step ELISA is based on two highly specific monoclonal antibodies against the amino acid sequence of EKAHD- β -GGR, where the aspartic acid residue (D) is β -isomerized. In order to obtain a specific signal in the Serum CrossLaps™ One Step ELISA, two chains of EKAHD- β -GGR must be cross-linked

Standards, control, or unknown serum samples are pipetted into the appropriate microtitre wells coated with streptavidin, followed by application of a mixture of a biotinylated antibody and a peroxidase-conjugated antibody. Then, a complex between CrossLaps™ antigens, biotinylated antibody and peroxidase-conjugated antibody is generated, and this complex binds to the streptavidin surface via the biotinylated antibody. Following the one-step incubation at room temperature, the wells are emptied and washed. A chromogenic substrate is added and the colour reaction is stopped with sulfuric acid. Finally, the absorbance is measured at 450 nm.

This pre-market notification demonstrates that the Serum CrossLaps™ One Step ELISA for the quantitative measurement of Type I Collagen C-telopeptides in plasma and serum is substantially equivalent to CrossLaps™ ELISA that was cleared by FDA in a previous submission (#K972788).

This pre-market notification includes clinical data demonstrating that

The CrossLaps™ ELISA assay is intended for in vitro diagnostic use as an indication of human bone resorption and may be used as an aid in :

A. Monitoring bone resorption changes of

1.) Anti-resorptive therapies in postmenopausal women:

- a) Hormone Replacement Therapies (HRT) with hormones and hormone like drugs
- b) Bisphosphonate therapies

2.) Anti-resorptive therapies in individuals diagnosed with osteopenia;

- a) Hormone Replacement Therapies (HRT) with hormones and hormone like drugs
- b) Bisphosphonate therapies

B. Predicting skeletal Response (Bone Mineral Density) in postmenopausal woman under going anti-resorptive therapies

- a) Hormone Replacement Therapies (HRT) with hormones and hormone like drugs
- b) Bisphosphonate therapies



DEPARTMENT OF HEALTH & HUMAN SERVICES

JUL -9 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Eva Gamwell Henriksen
Head of Regulatory Affairs
and Quality Assurance
OSTEOMETER BIOTECH A/S
HERLEV HOVEDGADE 207
DK-2730 HERLEV,
DENMARK

Re: K990843
Trade Name: Serum CrossLaps™ One Step ELISA
Regulatory Class: I reserved
Product Code: JMM
Dated: May 25, 1999
Received: May 27, 1999

Dear Ms. Henriksen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

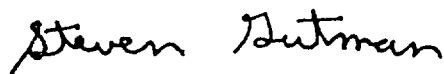
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, flowing style.

Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K990843

Device Name: Serum CrossLaps™ One Step ELISA

Indications for use:

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1.) Anti-resorptive therapies in postmenopausal women:

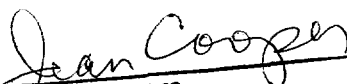
- a) Hormone Replacement Therapies (HRT) with hormones and hormone like drugs
- b) Bisphosphonate therapies

2.) Anti-resorptive therapies in individuals diagnosed with osteopenia;

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(Division Sign-Off)
Division of Clinical Laboratory
510(k) Number K990843

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

(Concurrence of CDRH, Office of Device Evaluation (ODE))

Prescription use 
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)